

What You Need to Know About the National Vaccine Injury Compensation Program (VICP)



February 2006



NOTE:

What You Need to Know About the National Vaccine Injury Compensation Program (VICP) is not a legal document. The official provisions are contained in the relevant laws, regulations and Court decisions. Because this provides only general information, you may wish to consult a lawyer.

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About the
National Vaccine
Injury Compensation
Program (VICP)**

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List of Acronyms and Terms

- Aids Qualifications and Aids to Interpretation
- DOJ U.S. Department of Justice
- HHS U.S. Department of Health and Human Services
- HRSA Health Resources and Services Administration
- VAERS Vaccine Adverse Event Reporting System
- VICP National Vaccine Injury Compensation Program
- Court U.S. Court of Federal Claims
- Table Vaccine Injury Table

What is the National Vaccine Injury Compensation Program (VICP)?

Vaccines save lives by preventing disease in the people who receive them. Most people who get vaccines have no serious problems. However, vaccines, like any medicines, can rarely cause serious problems, such as severe allergic reactions. In those rare cases, the VICP, which is a Federal program, provides compensation to people found to be injured by certain vaccines. The U.S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court).

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

Why and when was the VICP created?

In the early 1980s, news reports of serious side effects from the DTP (diphtheria, tetanus, pertussis) vaccine caused some to question the safety of the vaccine. Parents began filing many lawsuits against vaccine companies, doctors, and nurses. Some vaccine companies decided to stop making vaccines, which created vaccine shortages and threatened the Nation's health.

All of these problems led a group of doctors, public health organizations, vaccine companies and private citizens to encourage Congress to enact a new law to compensate those found to be injured by childhood vaccines. The National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the VICP, which began on October 1, 1988.

What vaccines are covered by the VICP?

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Influenza [given each year during the flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Polio (OPV or IPV)

- Pneumococcal conjugate (PCV)
- Rotavirus (RV)
- Varicella (VZV)
- Any combination of the vaccines above
- Additional vaccines may be added in the future

For a description of the diseases prevented by these vaccines, see page 15 in the Appendix.

How does the VICP work?

First, a claim must be filed by or on the behalf of the individual thought to be injured by a vaccine covered by the VICP. A claim is started by filing a legal document called a petition that is prepared by you or your lawyer to request compensation under the VICP. Anyone who files a claim is called a petitioner. The only form required is the Court's cover sheet for the claim. You may obtain a copy of the cover sheet and a sample claim by calling (202) 357-6400. Your claim should address the following information:

- who was injured by the vaccine;
- which vaccine caused the injury;
- when the vaccine was given;
- the city and State or country where the vaccine was given;
- the type of injury;
- when the first symptom of the injury appeared; and
- how long the effects of the injury lasted.

Your claim should also include your medical records and/or other appropriate documents, the Court's cover sheet, and the \$250.00 filing fee. If you are unable to pay this fee, call (202) 357-6400 for assistance. The original claim and two copies plus a \$250.00 filing fee should be sent to:

Clerk
U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005

One copy should be sent to:

Director, Division of Vaccine Injury Compensation
HRSA, Healthcare Systems Bureau
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857

Who may file a claim?

- You may file a claim if you received a vaccine covered by the VICP and believe that you have been injured by this vaccine.
- You may also file a claim if you are a parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP and believe that the person was injured by this vaccine.
- You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person's death resulted from the vaccine injury.
- You may file a claim if you are **not** a United States citizen.
- Some people who receive vaccines outside of the U.S. may be eligible for compensation. The vaccines must have been covered by the VICP and given in the following circumstances:
 - the injured person must have received a vaccine in the U.S. trust territories; or
 - if the vaccine was administered outside of the U.S. or its trust territories: 1) the injured person must have been a U.S. citizen serving in the military or a U.S. government employee, or have been a dependent of such a citizen; or 2) the injured person must have received a vaccine manufactured by a vaccine company located in the U.S. and returned to the U.S. within 6 months after the date of vaccination.

In addition, to be eligible to file a claim, the effects of the person's injury must have: 1) lasted for more than 6 months after the vaccine was given; or 2) resulted in a hospital stay **and** surgery; or 3) resulted in death.

What medical records and other documents are requested to ensure a timely review of my claim?

You must include certain medical records and/or other appropriate documents with the claim. If some medical records are unavailable, you must identify those records and explain why they are unavailable. The medical review and processing of the claim may be delayed if you do not include the appropriate medical records and other documents with the claim.

In order to ensure that your claim is processed in a timely manner, the VICP suggests that you include the following medical records and other documents when filing your claim with the Court and the Secretary of Health and Human Services, c/o Director, Division of Vaccine Injury Compensation.

Medical Records

1.* Prenatal and Birth Records

- Mother’s prenatal record
- Delivery record
- Birth Certificate
- Newborn hospital record including doctors’/nurses’ notes, and radiology/lab results
- Any hospitalization face sheet with final diagnosis

2. Medical Records Prior to Vaccination

- Clinic notes (such as Well Baby visits)
- Private doctor visits
- Growth charts/lab/radiology results
- Consultation reports and evaluations
- Developmental charts

3. Vaccination Record (if available)

- Lot number
- Manufacturer

4. Post-Injury Hospital/Emergency Treatment Records

- Admission/discharge summaries
- History and physical records
- Progress notes (including doctors’/nurses’ notes)
- Medication records
- Lab/radiology/EEG results
- Flow sheets (respiratory care/treatments)
- Consultation reports and evaluations

5. Post-Injury Outpatient Records

- History and physical records
- Progress notes (including doctors'/nurses' notes)
- Medication records
- Lab/radiology/EEG results
- Clinic notes
- All evaluations



6. Vaccine Adverse Event Reporting System (VAERS) form (if submitted)

7. Long Term Records (that apply to your injury)

- School records
- Consultation reports and evaluations
- Educational testing records
- Psychological testing records
- Police/ambulance records

8. Death Records (if applicable)

- Death Certificate
- Autopsy report (if done)
- Autopsy slides

*Note: Number 1 may be omitted if the injured person is an adult.

Do I need a lawyer to file a claim?

You do not need a lawyer to file a claim. However, since this is a legal process, most people use a lawyer. If certain minimal requirements are met, the VICP will pay your lawyer's fees and other legal costs related to your claim, whether or not you are paid for a vaccine injury or death. The VICP will not pay the fees of petitioners representing themselves, but will pay their other legal costs, whether or not the claim is paid as long as certain minimal requirements are met.

What are the deadlines to file a claim?

The general filing deadlines are:

- For an ***injury***, your claim must be filed within 3 years after the first symptom of the vaccine injury.
- For a ***death***, your claim must be filed within 2 years of the death and 4 years after the start of first symptom of the vaccine-related injury from which the death occurred.

When a ***new vaccine*** is covered by the VICP or when a ***new injury/condition*** is added to the Vaccine Injury Table (Table), claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change. The Table lists and explains injuries that are presumed to be caused by vaccines. For more details about the Table, visit www.hrsa.gov/vaccinecompensation.

For example, the hepatitis A vaccine was covered by the VICP as of December 1, 2004. Under the general filing deadline for an injury, the claim must be filed within 3 years after the first symptom of the vaccine injury. However, claims that do not meet the general filing deadlines must be filed by December 1, 2006 for injuries or deaths that occurred on or after December 1, 1996.

What is the process for filing a claim?

A summary of the claims process is provided below. The Court has documents which explain the process in more detail. To obtain these documents, you may visit the Court's Web site at www.uscfc.uscourts.gov/osmpage.htm or call (202) 357-6400. Most petitioners use a lawyer since this is a legal process, and the Rules of the Court are very specific and must be followed.

The process for filing a claim is:

1. the petitioner or petitioner's lawyer sends one original and two copies of the claim along with the medical records, other appropriate documents and a \$250.00 filing fee to the Court;
2. the petitioner or petitioner's lawyer sends one copy of the claim including the medical records and other appropriate documents to the Secretary of Health and Human Services, c/o Director, Division of Vaccine Injury Compensation;
3. the Court sends one copy of the claim and medical records to the DOJ;
4. HHS reviews the medical information in the claim and this review is sent to the DOJ lawyer who represents the Secretary of Health and Human Services;
5. the DOJ lawyer reviews the legal aspects of the claim and writes a report;

6. the HHS and DOJ reviews are combined into one report that is sent to the Court and petitioner or petitioner's lawyer;
7. the DOJ and petitioner or petitioner's lawyer take legal action to resolve the claim;
8. a "special master" (a lawyer appointed by the judges of the Court) decides if the claim will be paid and how much will be paid for the claim;
9. if the special master decides to pay the claim, the petitioner must make a decision to accept or reject the special master's decision in writing; and
10. the special master's decision may be appealed to a judge of the Court by the petitioner or HHS, then to the U.S. Court of Appeals for the Federal Circuit and, finally, to the U.S. Supreme Court.

What must be proved in order to be paid?

You must prove that:

- the injured person received a vaccine listed on the Table; and
- the first symptom of the injury/condition on the Table as defined in the Qualifications and Aids to Interpretation (Aids)* occurred within the time period listed on the Table; or
- the vaccine caused the injury; or
- the vaccine caused an existing illness to get worse (significantly aggravated).

In addition, the Court must determine that the injury or death did not result from any other possible causes.

What is the Vaccine Injury Table?

The Table makes it easier for some people to get compensation. The Table lists and explains injuries/conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries/conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occur within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found. For example, if you received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) within 4 hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury if no other cause is found.

If your injury/condition is not on the Table or if your injury/condition did not occur within the time period on the Table, you must prove that the vaccine caused the injury/condition. Such proof must be based on medical records or opinion, which may include expert witness testimony.

* The Aids define some of the injuries/conditions listed on the Table.

The Table and Aids change sometimes. To obtain a copy of the latest Table and Aids, visit the VICP Website at www.hrsa.gov/vaccinecompensation, or call 1-800-338-2382.

The following is a list of the vaccines covered by the VICP. These vaccines can be given alone or combined with other vaccines. The listing also includes the injuries/conditions associated with these vaccines and the time period in which the first symptom of these injuries/conditions must occur in order for the VICP to presume that the vaccine was the cause. For a description of the diseases prevented by these vaccines, see page 15 in the Appendix.

Important: This is only a summary of the Table. [The definitions of these injuries/conditions are in the Aids.]

<i>Vaccine</i>	<i>Injuries/Conditions</i>	<i>Time Period</i>
DIPHTHERIA	See pertussis and tetanus.	
HAEMOPHILUS INFLUENZAE TYPE b (Hib)	There are no Table injuries for this vaccine. ¹	Not applicable
HEPATITIS A (HAV)	There are no Table injuries for this vaccine. ¹	Not applicable
HEPATITIS B (HBV)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) ²	0-4 hours
INFLUENZA	There are no Table injuries for this vaccine. ¹	Not applicable
MEASLES, MUMPS, RUBELLA (MMR, MR, M, R)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) ²	0-4 hours
	Disorder of the brain (Encephalopathy) ²	5-15 days
MEASLES (MMR, MR, M)	A decrease in the number of platelets in the blood (Thrombocytopenic Purpura) ²	7-30 days
	Measles virus infection in an immunodeficient person ²	0-6 months
PERTUSSIS (DTaP, Tdap, DTP, P, DTP-Hib)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) ²	0-4 hours
	Disorder of the brain (Encephalopathy) ²	0-72 hours
PNEUMOCOCCAL CONJUGATE (PCV)	There are no Table injuries for this vaccine. ¹	Not applicable
POLIO		
INACTIVATED POLIO (IPV)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) ²	0-4 hours
ORAL POLIO (OPV) ³	1) Paralysis from the polio virus in the person who: – received the vaccine ² – received the vaccine and is unable to have a normal immune response to this vaccine (immunodeficient) ² – came in contact with a person who recently received the vaccine ²	0-30 days 0-6 months no time limit

<i>Vaccine</i>	<i>Adverse Event (Serious Side Effects)</i>	<i>Time Period</i>
POLIO (<i>continued</i>)		
ORAL POLIO (OPV) ³	2) Vaccine-strain polio infection in the person who: <ul style="list-style-type: none"> – received the vaccine² – received the vaccine and is unable to have a normal immune response to this vaccine (immunodeficient)² – came in contact with a person who recently received the vaccine² 	0-30 days 0-6 months no time limit
ROTAVIRUS		
LIVE, ORAL, RHESUS-BASED (RV) ³	The intestine or bowel folds into itself (Intussusception) ²	0-30 days
OTHER ROTAVIRUS (RV)	There are no Table injuries for this vaccine. ¹	Not applicable
RUBELLA (MMR, MR, R)	A persistent swelling of the joints (Chronic Arthritis) ²	7-42 days
TETANUS (DTaP, Tdap, DTP-Hib, DT, Td or TT)	A sudden, severe, and sometimes deadly allergic reaction (Anaphylaxis or Anaphylactic Shock) ²	0-4 hours
	Damage to a nerve or group of nerves in the under arm (Brachial Neuritis) ²	2-28 days
VARICELLA (VZV)	There are no Table injuries for this vaccine. ¹	Not applicable

ADDITIONAL VACCINES MAY BE ADDED IN THE FUTURE.

¹ When no injury is identified with this vaccine, the petitioner must prove that the injury was caused by the vaccine.

² In addition, any serious problems resulting from this injury/condition, including death.

³ This vaccine is no longer given in the U.S.

What are the types of payments?

For an *injury*, you may be paid:

- a reasonable amount for past and future nonreimbursable medical, custodial care, and rehabilitation costs, and related expenses (There is no limit on the amount a person with an injury may be paid for these types of expenses. Payments are based on your vaccine injury needs.);
- up to \$250,000 for actual and projected pain and suffering;
- lost earnings; and/or
- reasonable lawyers' fees and other legal costs or *legal costs, not fees, of petitioners representing themselves*, if your claim was filed on a reasonable basis and in good faith.

For a **death**, you may be paid:

- up to \$250,000 as a death benefit for the estate of the deceased; and
- reasonable lawyers' fees and other legal costs or *legal costs, not fees, of petitioners representing themselves*, if your claim was filed on a reasonable basis and in good faith.

Can I file a lawsuit outside the VICP?

Most of the time, you must **first** file and have your claim processed with the VICP before a civil lawsuit can be filed against the vaccine company or the person who gave the vaccine. If you would like to file a civil lawsuit outside of the VICP, contact a lawyer for advice.

What is the Vaccine Adverse Event Reporting System (VAERS)?

VAERS is a Federal program used to report injuries or illnesses that occur after a vaccine is given. Filing a VAERS report is not the same as filing a claim with the VICP. VAERS and the VICP are different programs. For more information about VAERS, call 1-800-822-7967 or visit their Web site at www.vaers.hhs.gov.

How do I obtain more information about the VICP?

National Vaccine Injury Compensation Program
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857; or
1-800-338-2382
www.hrsa.gov/vaccinecompensation

How do I obtain more information about filing a claim?

Clerk
U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005
(202) 357-6400
www.uscfc.uscourts.gov/osmpage.htm

How do I obtain a list of lawyers?

Clerk

U.S. Court of Federal Claims

717 Madison Place, N.W.

Washington, DC 20005

(202) 357-6400; or

Your State or local bar association

Appendix

Description of Diseases Prevented by VICP Covered Vaccines

<i>Vaccines</i>	<i>Description of Diseases Prevented by Covered Vaccines</i>
DIPHTHERIA	A bacterial disease which can cause a thick covering in the back of the throat, and can lead to breathing problems, paralysis, heart failure, and even death.
HAEMOPHILUS INFLUENZAE TYPE B	A bacterial disease which can cause meningitis, pneumonia, severe swelling in the throat (making it hard to breathe), infections of the blood, joints, bones, and covering of the heart, and death. Meningitis is an infection of the covering of the brain.
HEPATITIS A	Hepatitis A virus can cause mild “flu-like” illness, jaundice, severe stomach pains and diarrhea, and can lead to a serious liver disease.
HEPATITIS B	Hepatitis B virus can cause short-term (acute) illness, and can lead to loss of appetite, diarrhea and vomiting, tiredness, jaundice (yellow skin or eyes), and pain in muscles, joints, and stomach. It can also cause long-term (chronic) illness which can lead to liver damage (cirrhosis), liver cancer and/or death.
INFLUENZA	Influenza virus can cause fever, sore throat, chills, fatigue, cough, headache, and muscle aches. It is a very contagious disease which spreads from infected persons to the nose or throat of others.
MEASLES	Measles virus can cause rash, cough, runny nose, eye irritation which can lead to ear infection, pneumonia, seizures (jerking and staring spells), brain damage, and death.
MUMPS	Mumps virus can cause fever, headache, and swollen glands, and can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

(Continued)

Vaccines

Description of Diseases Prevented by Covered Vaccines

PERTUSSIS (WHOOPIING COUGH)

A bacterial disease which can cause coughing spells so bad that it is hard to eat, drink, or breathe, and can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death. It is also called Whooping Cough.

PNEUMOCOCCAL CONJUGATE

A bacterial infection which can lead to serious illness and death, and is the leading cause of bacterial meningitis in the United States.

POLIO

Polio virus can cause paralysis (can't move arm or leg) or death by paralyzing the muscles that help people breathe.

ROTAVIRUS

Rotavirus can cause diarrhea which can lead to dehydration and other problems in children.

RUBELLA

Rubella virus can cause rash, mild fever, and arthritis (mostly in women). It is also called German Measles.

TETANUS

A bacterial disease which can cause painful tightening of the muscles, usually all over the body, and can lead to "locking" of the jaw so the victim cannot open his mouth or swallow. Tetanus enters the body through cuts or wounds. It is also called Lockjaw.

VARICELLA (CHICKENPOX)

Varicella virus can cause a rash, itching, fever, and tiredness, and can lead to severe skin infection, scars, pneumonia, brain damage, or death. It is also called Chickenpox. The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Healthcare Systems Bureau
Division of Vaccine Injury Compensation
<http://www.hrsa.gov/vaccinecompensation>
1-800-338-2382